

### **REMARKS/ARGUMENTS**

Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. The proposed amendment places the claims in better form for appeal. Additionally, this amendment addresses items brought up by the examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

Support for the new and amended claims can be found throughout the specification, including Examples and originally filed claims. The weight percents of the monomer subunits in the bipolymer and terpolymer have been corrected to refer to mole percents in certain claims (e.g., 4, 5, 16, and 17) based on the data presented in Table 1, which clearly specifies mole percents for the monomer subunits. One of skill in the art would understand this to be a typographical error in the claims.

Also, the specification has been amended to correct certain errors that would be clear to one of skill in the art.

#### **35 U.S.C. §103 Rejections**

The Examiner rejected claims 1-13 and 15-21 under 35 U.S.C. §103(a) as being unpatentable over Benz et al. (U.S. Publication No. 2003/0162905) in view of Shalaby et al. (U.S. Publication No. 2003/0199964) and Van Krevelen ("Properties of Polymers," 1990, Elsevier, 3<sup>rd</sup> Edition, Chapter 7, pages 189-225). The Examiner rejected claims 14 and 22-24 under 35 U.S.C. §103(a) as being unpatentable over Benz et al. (U.S. Publication No. 2003/0162905) in view of Shalaby et al. (U.S. Publication No. 2003/0199964) and Van Krevelen ("Properties of Polymers," 1990, Elsevier, 3<sup>rd</sup> Edition, Chapter 7, pages 189-225), as applied to claim 13, and further in view of Sirhan et al. (U.S. Publication No. 2002/0082677).

Each of the independent claims having been amended, these rejections are rendered moot. Insofar as they apply to the presently pending claims, they are respectfully traversed. This also applies to Lyu et al. (U.S. Publication No. 2004/0047911), which the Examiner did not include in these rejections.

Applicants submit that the presently pending claims are not obvious in view of the cited art in any combination (including Lyu et al.). For example, there is no teaching or suggestion of the significance of the presence of vinyl acetate in both the bipolymer and terpolymer. As stated in the present application (e.g., Paragraph [0086]), “. . . the present inventors have discovered that the pendent group size on hydrophobic polymers such as alkyl esters can affect polymer dispersive forces . . . which in turn can affect release kinetics and Tg. However, Tg can also be affected by monomer polarity . . . [and] . . . [i]n one embodiment of the present invention vinyl acetate is used to modulate polymer polarity. Vinyl acetates have polar groups that increase the intermolecular forces and decrease free volume. As free volume decreases, Tg increases.” There is no teaching or suggestion in the combination of cited art of the contribution of vinyl acetate in both the bipolymer and terpolymer to the Tg. Also, there is no teaching or suggestion in the combination of cited art of the recited bipolymer and terpolymer (e.g., as specifically recited in claims 1 and 13), which include vinyl acetate and an alkyl methacrylate.

It is respectfully submitted that there would be a significantly large number of combinations of bipolymers and terpolymers, and a significantly large number of polymer blends, that would result from the various combinations of art cited by the Examiner. As stated in the United States Court of Appeals for the Federal Circuit 2007-1223 *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc., and Mylan Pharmaceuticals, Inc.*, March 31, 2008, the situation in *KSR International Co. v. Teleflex Inc.* 127 S. Ct. 1727, 1742 (2007) regarding finite options (“[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp”), “posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinary skilled artisan of obviousness” (*Ortho-McNeil Pharmaceutical*, Part IV of opinion). In the present situation, there are not a small number of options.

It is respectfully submitted that this rejection was made by impermissible hindsight reconstruction, that is, by picking and choosing from each document that which

supports these rejections. One cannot “simply [to] engage in a hindsight reconstruction of the claimed invention, using the Applicant’s structure as a template and selecting elements from references to fill the gaps.” *In re Gorman*, 933 F.2d 982, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991). It is respectfully submitted that the Examiner cannot simply retrace the path of the inventor with hindsight, but must consider the number and complexity of the alternatives.

Simply because these documents exist is not sufficient reason to combine them in the manner outlined by the Examiner. It is respectfully submitted that Applicants’ claims have provided the roadmap for this combination of documents. Furthermore, it is respectfully submitted that the Examiner has made conclusory statements based on a rationale that could only have been reached using Applicants’ claims as the guide.

In *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705, 82 USPQ2d (BNA) 1385 (2007), the U.S. Supreme Court stated that “[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” Furthermore, the U.S. Supreme Court acknowledged that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* at 418, 127 S. Ct. 1741, 167 L. Ed. 2d at 722, 82 USPQ2d (BNA) at 1389.

In the present Office Action, this is precisely what has occurred – various elements of the claims have been extracted from the jungle of prior art in the polymer and medical device fields without an articulated reasoning and some rationale beyond merely stating that these elements exist. To the extent that the Examiner has provided a rationale, such could only have been devised using Applicants’ claims and teachings of the invention as the guide. This is insufficient to meet a *prima facie* case of obviousness.

Accordingly, the present obviousness assessment merely reduces Applicants’ invention into its component parts and applies a document corresponding to each component. This type of assessment clearly imports hindsight into the obviousness determination by using the invention as a roadmap. The U.S. Supreme Court cautioned

against just this, again in *KSR*, stating, “A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” *Id.* at 421, 127 S. Ct. 1742, 167 L. Ed. 2d at 724, 82 USPQ2d (BNA) at 1397 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) (warning against a “temptation to read into the prior art the teachings of the invention in issue” and instructing courts to “guard against slipping into the use of hindsight” (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412, 141 USPQ (BNA) 549 (6<sup>th</sup> Cir. 1964)))).

Since the Supreme Court’s decision in *KSR*, the Federal Circuit has reaffirmed the *prima facie* obviousness test for chemical compounds (and, by analogy, chemical compositions) in *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Lt.*, No. 06-1329, slip op. at page 9 (Fed. Cir. June 28, 2007) (“... in order to find a *prima facie* case of unpatentability ... a showing that the ‘prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention’ was also required.”). The Federal Circuit stated that “[w]hile the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation (‘TSM’) test in an obviousness inquiry, the Court acknowledged the importance of identifying ‘a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does’.” *Id.* at p. 10. The Federal Circuit further stated that ... “in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.” *Id.* at p. 10. It is respectfully submitted that there is no such reason in the present situation. There has been no reason provided that would cause one of skill in the art to select the recited elements and form the claimed combination out of the myriad of possible combinations that flow from the combination of components in the cited art.

For at least these reasons, Applicants respectfully submit that pending claims comply with the requirements of 35 U.S.C. §103(a) and request that the rejections presented herein be reviewed and reversed.

### **Conclusion**

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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